



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/675,011

09/30/2003

Lynn Dickey

040989/267934

5538

826

7590

12/24/2008

ALSTON & BIRD LLP

BANK OF AMERICA PLAZA

101 SOUTH TRYON STREET, SUITE 4000

CHARLOTTE, NC 28280-4000

EXAMINER

ZHENG, LI

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

12/24/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/675,011	<b>Applicant(s)</b> DICKET ET AL.	
	<b>Examiner</b> LI ZHENG	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 82-84 and 87-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 82-84 and 87-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 25, 2008 has been entered.

2. Claims 82-84 and 87-94 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejections and objections not set forth in this action are withdrawn.

***Claim Rejections - 35 USC § 103***

5. Claims 82-84 and 87-92 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stomp et al. (1999, WO 99/07210) further in view of Wong et al.

Art Unit: 1638

(1992, Plant Molecular Biology 20:81-93), Buzby et al. (1990, The Plant Cell 2:805-814) and Stiekema et al. (1983, Nucleic Acid Research 11:8051-8061), for the reasons of record stated in the Office action mailed February 7, 2008. Applicants traverse in the paper filed September 25, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that in making an assessment of the significance of citations as prior art, one must take into account the degree to which reliable prediction can be made in the art and that to "try" is not equivalent to reliable prediction in duckweed expression system (response, page 5, 3<sup>rd</sup> paragraph). Applicants argue that neither Buzby et al. nor Wong et al. bridge the gaps between Stomp et al. and the pending claims by guiding one of ordinary skill in the art to SEQ ID NO: 16 due to unpredictability of the art (response, the paragraph bridging pages 4-5).

The Office contends that the rejection is based on the reasonable expectation of success. It is known in the art that 5' UTL of RbcS genes from numerous plant species can be used to enhance expression. Therefore, there is a reasonable expectation of success for the 5' leader sequence from RbcS 5B gene from *L. gibba* as taught by Buzby et al. Given that the expression host in Stomp et al. is also a duckweed, the 5' leader sequence of Buzby et al. thus becomes an obvious choice as a 5' UTL to be used to enhance expression as taught by Wong et al.

Applicants further argue that a person skilled in the art would not look to Buzby et al. to enhance protein expression in duckweed because Buzby et al. only focused on

Art Unit: 1638

the binding activity of LRF-1 to highly related 5' UTL of RbcS that do not include SEQ ID NO: 16 (response, page 6, 2<sup>nd</sup> paragraph).

The Office contends that Buzby et al. is provided as a reference to teach a 5' UTL comprising SEQ ID NO: 16. The LRF-1 binding activity of Buzby et al. is unrelated to the instant rejection.

Applicants further argue that Wong et al. did not disclose SEQ ID NO: 16 and that a comparison of 5' UTL of Wong et al. with SEQ ID NO: 16 reveals that they are structurally distinct. Applicants conclude again that the effect of SEQ ID NO: 16 on enhancing protein expression could not be predicted (response, page 6, 3<sup>rd</sup> paragraph).

The Office contends that the 5' UTL of RbcS genes from various plant species may have differences at nucleotide sequence level, however, the function, i.e. enhancing gene expression, is highly conserved. The differences in nucleotide sequence may contribute to the efficacy as an expression enhancer, however, on the other hand it further motivates a person with ordinary skill in the art to use 5'UTL of RbcS gene 5B from a duckweed for enhancing heterologous expression of genes in a duckweed plant.

Finally, Applicants argue that the Examiner appeared to simply pick and choose from the citation only so much of each as will support the given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to a person skilled in the art and that there is no citation contemplated or disclosed enhancing protein expression in duckweed with SEQ ID NO: 16 in the absence of hindsight reasoning (response, page 7, 2<sup>nd</sup> paragraph).

The Office disagrees. It is clear to a person with ordinary skill in the art that Stomp et al. teach a method of producing a biologically active recombinant polypeptide in a duckweed culture; that Wong et al. teach the 5' leader sequence from RbcS gene of Arabidopsis; and that the 5' UTL fragment from duckweed can be obtained from the teaching of Buzby et al. Given the general knowledge that 5' leader sequence from various RbcS genes can be used to enhance expression in plants (e.g. leader sequence from soybean Rbcs as taught in US Patent Number 6,329,574) with different efficacy, it would be choose a duckweed 5' UTL from RbcS gene to enhance the heterologous gene expression in a duckweed host.

6. Claims 82-84 and 87-94 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Stomp et al. (1999, WO 99/07210) further in view of Wong et al. (1992, Plant Molecular Biology 20:81-93), Buzby et al. (1990, The Plant Cell 2:805-814), Yu et al. (1995, U.S. Patent No. 5460952), Park et al. (1997, The Journal of Biological Chemistry 272:6876-6881) and Stiekema et al. (1983, Nucleic Acid Research 11:8051-8061) , for the reasons of record stated in the Office action mailed February 7, 2008. Applicants traverse in the paper filed September 25, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar argument as presented for the above rejection under 35 U.S.C. 103(a) (response, page 5, 2<sup>nd</sup> paragraph). For the same reason as discussed above, the rejection is maintained.

***Double Patenting***

7. Claims 82-84 and 87 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17 of U.S. Patent No. 6,815,184 (hereafter '184) in view of Wong et al. (1992, Plant Molecular Biology 20:81-93), and Buzby et al. (1990, The Plant Cell 2:805-814) , for the reasons of record stated in the Office action mailed February 7, 2008. Applicants traverse in the paper filed September 25, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants present similar argument as presented for rejections under 35 U.S.C. 103(a) (response, the paragraph bridging pages 7-8). For the same reason as discussed above, the rejection is maintained.

8. Claims 82-84 and 87-94 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 8-10, 23, 26-29 of copending Application No. 10/794,615 (hereafter '615) , for the reasons of record stated in the Office action mailed February 7, 2008. Applicants traverse in the paper filed September 25, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants do not present any argument and therefore the rejection is maintained. However, Applicants' intention to address the filing of a terminal disclaimer

Art Unit: 1638

when the application is otherwise in condition for allowance is acknowledged (response, page 8, 2<sup>nd</sup> paragraph).

9. Claims 82-84 and 87 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 11/778,480, which is a continuation application of the abandoned application of '846, in view of Wong et al. (1992, Plant Molecular Biology 20:81-93), and Buzby et al. (1990, The Plant Cell 2:805-814) , for the reasons of record stated in the Office action mailed February 7, 2008. Applicants traverse in the paper filed September 25, 2008. Applicants' arguments have been fully considered but were not found persuasive.

Applicants do not present any argument and therefore the rejection is maintained. However, Applicants' intention to address the filing of a terminal disclaimer when the application is otherwise in condition for allowance is acknowledged (response, page 8, 3<sup>rd</sup> paragraph).

### ***Summary***

No claim is allowed.



Art Unit: 1638

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 5:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Li Zheng/  
Examiner, Art Unit 1638